

## **AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. – 137. (canceled).

138. (new) A unit dose of a controlled release pharmaceutical formulation comprising a rubbery matrix including a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active ingredient.

139. (new) The unit dose of claim 138, wherein said active agent is selected from the group consisting of an opioid, a stimulant, a barbiturate, an anti-depressant a dissociative anaesthetic, and any two or more of the foregoing.

140. (new) The unit dose of claim 139, wherein said active agent is oxycodone.

141. (new) The unit dose of claim 138, which comprises multiparticulates.

142. (new) The unit dose of claim 138, wherein said matrix includes at least one other polymer to modify release.

143. (new) The unit dose of claim 142, wherein said other polymer is selected from the group comprising an alkyl cellulose or a water insoluble ammonium methacrylate copolymer.

144. (new) The unit dose of claim 143, wherein said other polymer is ethyl cellulose.

145. (new) The unit dose of claim 144, wherein said amount of ethyl cellulose is 10 to 50% by weight of the formulation.

146. (new) The unit dose of claim 138, which contains the following amounts of ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

147. (new) The unit dose of claim 138, which comprises up to 60% w/w of said active agent, 15 to 50% w/w of neutral poly(ethyl acrylate, methyl methacrylate) copolymer; 5 to 60% w/w of ethyl cellulose; and 7.5 to 20% of plasticiser.

148. (new) The unit dose of claim 147, which further contains 5 to 60% of an insoluble ammonium methacrylate copolymer.

149. (new) The unit dose of claim 148, which contains 35 to 50% of an insoluble ammonium methacrylate copolymer which is of low permeability and/or 5 to 30% of an ammonium methacrylate copolymer which is highly permeable.

150. (new) The unit dose of claim 138, which contains a bulking agent.

151. (new) The unit dose of claim 138, which contains an opioid and an opioid antagonist.

152. (new) The unit dose of claim 151, which comprises 120 to 300 mg of oxycodone multiparticulates and 125 to 175 mg of oxycodone antagonist multiparticulates.

153. (new) The unit dose of claim 138, which contains oxycodone and naltrexone.

154. (new) The unit dose of claim 138, which contains oxycodone in an amount selected from the group consisting of 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 120 mg or 160 mg of oxycodone.

155. (new) The unit dose of claim 138, suited for once a day dosing.

156. (new) The unit dose of claim 155, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate *in vitro*, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH between 1.6 and 7.2 at 37°C of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80% at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

157. (new) The unit dose of claim 156, wherein the peak plasma level of oxycodone obtained *in vivo* occurs at 2 hours to 17 hours after administration of the dosage form.

158. (new) The unit dose of claim 155, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate *in vitro*, when measured using the USP Basket Method <<7 11>> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C unit dose form with detection by HPLC with UV at 206 nm wavelength; from 10 to 30% at 1 hour; from 20 to 35% at 2 hours; from 35 to 75%, at 8 hours; and greater than 50% at 16 hours.

159. (new) The unit dose of claim 138, suited for twice a day dosing.

160. (new) The unit dose of claim 159, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate *in vitro*, when measured by the USP Paddle Method (see the U.S. Pharmacopoeia XXII 1990) at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of between 12.5 and 42.5% (by wt) oxycodone released after 1 hour, between 25 and 56% (by wt) oxycodone released after 2 hours, between 45 and 75% (by wt) oxycodone released after 4 hours and between 55 and 85% (by wt) oxycodone released after 6 hours.

161. (new) The unit dose of claim 159, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate *in vitro*, when measured using the USP Basket Method << 7 11 >> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 0 to 40% at 1 hour; from 20 to 70%, at 2 hours; from 40 to 80%, at 3 hours; from 60 to 95%, at 4 hours; and greater than 70% at 5 hours.

162. (new) The unit dose of claim 161, wherein the peak plasma level of oxycodone obtained *in vivo* occurs between 2 and 4.5 hours after administration of the dosage form.

163. (new) The unit dose of claim 138, wherein said controlled release pharmaceutical formulation is obtained by melt extrusion.

164. (new) The unit dose of claim 138, which shows at least one of the following characteristics (a) to (e) when tested by a test method comprising admixing a dosage amount of multiparticulates with 10 ml of the liquid in a glass flask and shaking at 500 to 600 oscillations per minute for 15 minutes using a Stuart Scientific Shaker Model SF1:

- a. 15 minutes shaking in water at room temperature: less than 7.5% release of active agent;

- b. 5 minutes standing in water at 50°C followed by 15 minutes shaking at the same temperature: less than 15% release of active agent;
- c. 5 minutes standing at 75°C followed by 15 minutes shaking at the same temperature: less than 20% release of active agent;
- d. 5 minutes standing at 100°C followed by 15 minutes shaking at the same temperature: less than 25% release of active agent;
- e. 15 minutes shaking in 40% ethanol at room temperature: preferably less than 25% release of active agent.